K082197

AUG 22 2008

510(k) Summary: K082197

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For the Portrait® PSR³ System

General Information

Submitter:	Rhytec, Inc. 130 Turner Street Building Two Waltham, MA 02453
Contact Person:	Robert Zoletti Rhytec, Inc. 130 Turner Street Building Two Waltham, MA 02543 Telephone: 781-419-9482 Email: rzoletti@rhytec.com
Summary Preparation Date:	August 20, 2008

Names

Trade Name:	Portrait® PSR³ System
Classification Name:	Electrosurgical cutting and coagulation device
Product Code:	GEI

Legally Market Predicate Devices
K073111 Portrait® PSR³ System

Device Description
The Portrait® PSR³ System is an electro-surgical device for use in dermatological applications. The effect of the device is achieved by heating the outer layer of the skin so that part or all of the epidermis becomes non-viable and there is controlled damage to the underlying dermis. Similar biological changes are produced as with established laser–based and RF-based dermatological surgical and skin resurfacing technologies.

The system includes:

- Portrait PSR³ Generator - a mobile unit comprising a trolley and lift-out section referenced to as a "generator section". Treatment parameters are displayed on the control panel. The unit is powered by a 110/230 VAC standard wall socket.
- Footswitch - single pedal unit for activation
- Handpiece and Cable Assembly – carries RF power and Nitrogen gas to the Nozzle.

- Treatment Pack comprising a disposable Nozzle that is connected to the Handpiece and an electronic "treatment pack key" that is used by the generator to ensure the Nozzle is not used beyond its validated operational life. The instrument does not touch the skin during treatment.
- Nitrogen Gas Cylinder -- the gas is provided in a cylinder housed in the generator enclosure. Refill cylinders containing the required purity of Nitrogen are obtained by the user from a commercial gas supplier.

Indications for Use Statement
The Portrait® PSR^3 System is intended for treatment of the following dermatological conditions:

- Treatment of wrinkles and rhytides
- Superficial skin lesions
- Actinic Keratosis
- Viral Papillomata
- Seborrhoeic Keratosis
- Acne Scars

The indications have not been changed from the cleared submission, K073111.

Technological Characteristics
The technology involved in the Portrait® PSR^3 System has not been changed.

UHF energy from the generator converts Nitrogen gas into plasma within the Handpiece. The plasma emerges from the Nozzle at the distal end of the Handpiece and is directed onto the skin to be treated. Rapid heating of the skin occurs as the excited gas gives up energy to the skin. Through the combination within the Handpiece of precisely controlled energy and Nitrogen gas, plasma pulses are produced that will give predictable tissue effects.

The Portrait® PSR^3 System with the modified software and hardware provides a 4 Joule treatment as two consecutive pulses within 40 milliseconds. This is an additional menu selection that supplements the current mode of supplying 4 Joules as one continuous pulse in 15.4 milliseconds.

Substantial Equivalence Comparison
The Portrait® PSR^3 System with the modification is equivalent to the Portrait® PSR^3 System cleared in K073111. The modified software and hardware provide an alternative method of delivering a 4 Joule treatment pulse.

Clinical and Non-Clinical Data
Tests were conducted using a calorimeter to measure the energy delivered. The modified mode provides 4 Joules within the product specification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 2008

Rhytec Incorporated
% Mr. Robert Zoletti
Director, Regulatory Affairs
and Quality
130 Turner Street, Building 2
Waltham, Massachusetts 02453

Re: K082197
Trade/Device Name: Portrait® PSR^3 System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 31, 2008
Received: August 04, 2008

Dear Mr. Zoletti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **K082197**

Device Name: Portrait® PSR^3 System

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- Treatment of wrinkles and rhytides
- Superficial skin lesions
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- Viral papillomata
- Seborrhoeic keratosis
- Acne scars

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082197